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Rudi Brands

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RUDI BRANDS

Appeal 2010-000543
Application 09/582,342
Technology Center 1600

Before LORA M. GREEN, FRANCISCO C. PRATS, and
STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for preparing cells to be used in producing a biological. The Patent Examiner rejected the claims on the ground of obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Claims 39-44, which are all the pending claims, are on appeal. Claim 39 is representative and reads as follows:

39. A method for the preparation of cells for use in the production of a biological, the method comprising culturing cells to a desired cell volume of a preproduction batch, wherein the cells are anchorage dependent cells, where after in a repeated discontinuous process:
- a) a first part of the cells of the preproduction batch is used for the preparation of at least one production batch, and
 - b) the remaining part of the cells of the preproduction batch is used as a seed for the preparation of at least one subsequent preproduction batch.

The Examiner rejected claims 39-44 under 35 U.S.C. § 103(a) as unpatentable over Griffiths,² in light of the history of sourdough recited in “Friendship Cake/Bread History”³ and “Amish Friendship Bread.”⁴

² Bryan Griffiths et al., *Scale-Up of Suspension and Anchorage-Dependent Animal Cells*, in 75 METHODS IN MOLECULAR BIOLOGY, BASIC CELL CULTURE PROTOCOLS 2nd ed., edited by J.W. Pollard et al., Humana Press Inc., Totowa NJ, 59-75 (1997).

³ “Friendship Cake/Bread History,” Recipe Circus.com, The Recipe Circus, accessed by the Examiner 6 August 2007 at http://recipecircus.com/recipes/philocrates/Hint/Friendship_CakeBread_History.html. (Ans. 4.)

⁴ “Amish Friendship Bread,” Wikipedia.org., 17 July 2007, Wikimedia Foundation, Inc., accessed by the Examiner 6 August 2007 at http://en.wikipedia.org/wiki/Amish_Friendship_Bread. (Ans. 4.)

Claims 40-44 have not been argued separately and therefore stand or fall with claim 39. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS

The Issue

The Examiner's position is that Griffiths described a method of culturing anchorage cells for use in the production of a biological. (Ans. 4-5.) According to the Examiner, Griffiths described "passaging" the preproduction batch cells, but "did not explicitly state a first portion of the cells are replated as a seed for a subsequent 'preproduction batch,' and a second portion of the recovered cells are transferred and used as a 'production batch' specifically for the production of biological products." (*Id.* at 5.)

Notwithstanding Griffiths' failure to explicitly describe the claimed procedure, the Examiner maintained that it "would have been routinely performed by one of ordinary skill in the art," and concluded that Appellant's invention was *prima facie* obvious. The Examiner explained: "[d]ue to the fact that such is so well known, it is not routinely included in written protocols intended for artisans of ordinary skill. To exemplify its common place in the art, processes for production of sourdough . . . [are] referenced." (*Id.*) The Examiner further found that

[i]n the method of Griffiths et al, one of ordinary skill in the art would have been motivated to retain and reseed at least one portion of the culture as a seed for future 'preproduction batches' in order to continue the cell line, thereby saving money (by not needing to purchase a subsequent cell culture seed), and increasing the amount of biological product which can ultimately be produced (as the initial culture is not exhausted

after the first round of biological product production, but a small portion can be retained, passaged and expanded, so as to provide a cell source for future ‘production batches’).

(*Id.* at 6.)

Appellant contests the rejection on these grounds:

- (1) the cited references fail to teach or suggest all the claim limitations (App. Br. 11-12);
- (2) the Examiner failed to meet the burden under the teaching-suggestion-motivation rationale (*id.* at 12);
- (3) the art teaches away from the claimed method (*id.* at 13); and
- (4) the claimed method satisfied a long-felt need (*id.* at 14-16).

Principles of Law

“One of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 419-420 (2007). “In other words, the nature of the problem called for exactly the solutions in the prior art.” *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1339 (Fed. Cir. 2005) (affirming obviousness where motivation was found in the knowledge of those skilled in the art at the time, and where the nature of the problem also supplied a motivation). *Accord*, *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1366 (Fed. Cir. 2006) (“the ‘evidence’ of motive will likely consist of an explanation of the well-known principle or problem-solving strategy to be applied”).

A prior art reference is said to teach away from an Applicant's invention "when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed." *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

Analysis

First, we agree with the Examiner's findings concerning the scope and content of the prior art, with one exception. (See Ans. 4-7.) The Examiner seems to have interpreted Griffiths' use of the term "passaging" as meaning "wherein 'passaging' involves splitting the culture and re-seeding and culturing at least one portion of the split culture." (*Id.* at 4-5.) Griffiths did not explicitly explain "passaging" in that way, nor do we see evidence that "passaging" was implicitly intended in that way. We think "passaging" may include that meaning, but it is more likely a broader term. However, the Examiner next identified splitting the cell culture into a production batch and a reseeded batch as a point of difference between Griffiths and the claimed method. We agree with that finding, and that it corrects the possible error associated with the interpretation of "passaging."

We also agree with the Examiner's further findings and reasoning explaining why a person of ordinary skill in the art would have found it obvious to save a seed culture for future production batches. (See, e.g., Ans.

6.) The Examiner's reasoning accords with precedent. *E.g.*, *KSR*, 550 U.S. at 419-420; *Princeton Biochemicals*, 411 F.3d at 1339; *DyStar*, 464 at 1366. We find the Examiner's logic compelling, and reject Appellant's argument that the prior art and the knowledge in the art do not account for all the steps in the claimed method. Appellant has not persuasively shown that there is a reasonable way to read the prior art to "teach away" from the idea of saving a seed culture. *See Gurley*, 27 F.3d at 553; *Fulton*, 391 F.3d at 1201.

Finally, we are not persuaded that Appellant has shown that the invention solves a long-felt but unsolved need. Appellant offers no objective evidence on this point, but "precedent requires that the applicant submit actual evidence of long-felt need, as opposed to argument." *In re Kahn*, 441 F.3d 977, 990 (Fed. Cir. 2006). As a general practice, saving seed is thousands of years old, and making sourdough bread by saving a portion of the culture is also old. We think the Examiner has the better position.

SUMMARY

We affirm the rejection of claims 39-44 under 35 U.S.C. § 103(a) as unpatentable over Griffiths and the history of sourdough recited in Friendship Cake/Bread History and Amish Friendship Bread.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON DC 20001-4413